

**REMARKS**

Claims 1-15 are presently pending in the instant Application. In the instant Amendment, Claims 1 and 15 have been amended. Support for amended Claims 1 and 15 can be found generally throughout the instant Specification, and particularly on page 5, lines 8-9; page 5, lines 10-12; and in Claims 1-5 as originally filed. In Claim 15, at the end of step (c), "sample" was added as it was inadvertently omitted when the claim was originally presented.

***The Invention is Definite***

Claims 1-15 have been objected to under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the Invention.

The Examiner has asserted that claims 1 and 15 do not encompass a complete process because there is no standard of C-peptide measured. This rejection is respectfully traversed. Claims 1 and 15 both recite the step of detecting or determining the presence of C-peptide containing impurity in the sample. This step includes a number of actions that are well known to one of ordinary skill in assay art. Such persons would well know ways of determining protein concentrations in samples, including the way disclosed as a preferred example by the instant specification, i.e., using a standard curve, and such well known aspects of claims need not be stated as though the claim were a laboratory protocol. Accordingly, it is respectfully submitted that one skilled in the art would know that determining protein concentrations is a ordinary part of detecting or determining the presence of C-peptide containing impurity in the sample and

would know ways, including the use of a standard curve, to accomplish this aspect of the step. Hence, this objection should be withdrawn.

The Examiner has asserted that "adding tracer" in step (a) of Claims 1 and 15 is vague and indefinite. Step (a) of Claims 1 and 15 has been amended to specify that the tracer is a C-peptide tracer. Accordingly, this objection should be withdrawn.

The Examiner has asserted that in step (a) of Claims 1 and 15 it is unclear whether the tracer is labeled and whether the tracer or the second antibody is measured. Both Claims 1 and 15 have been amended such that the second antibody is not labeled making it clear that only the tracer is measured. Regarding the asserted lack of clarity with respect to whether the tracer is labeled, Applicants respectfully submit that this is clear by the very use of the term tracer. All tracers necessarily have some attribute that enables them to be traced. If they cannot be traced, they are not a tracer. The specification provides, as a preferred example, a chemiluminescent tracer, however, it will occur to one of ordinary skill in the art that tracers other than chemiluminescent tracers can be used that are encompassed by the instant invention. Hence, the use of the term tracer is clear and this objection should be withdrawn.

The Examiner has asserted that the function of the second antibody of claims 1 and 15 (c) is unclear. Claims 1 and 15 have been amended to recite that the C-peptide second antibody bead is capable of capturing the antibody specific of the C-peptide containing impurity making it clear that the second antibody is for capturing the first antibody. Accordingly, this objection should be withdrawn.

The Examiner has asserted that claim 1(d) is unclear because it is unclear how to determine the presence of the C-peptide-containing impurities. As stated above in response to

the first objection, exactly how this step is accomplished is within the knowledge of one of ordinary skill in the art and a preferred example is detailed in the specification. Such persons would know ways of determining protein concentrations in samples, and such well-known aspects of claims need not be recited. Accordingly, it is respectfully submitted that one skilled in the art know how to accomplish this aspect of step (d) in Claims 1 and 15. Hence, this objection should be withdrawn.

In the light of the above, it is respectfully submitted that all objections be withdrawn, and the Claims be allowed to issue.

The Commissioner is hereby authorized to charge any additional fees which may be required by this paper, or credit any overpayment to Deposit Account no. 18-1982.

### CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,

  
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